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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 1998

WARNING LETTER

Ref:OC:I1-1789

via FEDERAL EXPRESS

Mr. Stephen D. Santomenna
Operations Manager/LSO
Image Engineering Corporation
10 Beacon Street
Somerville, Massachusetts 02143

Mr. David Melanson
Project Development Director
VIEJAS Casino/Outlet Center
5000 Willows Road
Alpine, California 92101

Dear Messrs. Santomenna and Melanson:

This letter is written to advise you of items of noncompliance with the laser product performance standard and the conditions of the Image Engineering variance, Number 80P-0157, encountered during a Food and Drug Administration inspection of your laser light show installation at Viejas Outlet, 5000 Willows Road, Alpine, California 91901.

21 CFR 1040.11(c). The laser light show is Class IV which exceeds the limits for demonstration products in the cited paragraph and

a) Variance 80P-0157, Condition 7. The laser light show was not being operated by an employee of the variance holder. This occurred on the night of May 20, 1998 and remained partially true even on June 1, 1998 when the show was operated by an operator employed by Image Engineering, but there were several operators to permit them to switch off and only one was so employed.

b) Further, the operator's training was inadequate in that he failed to recognize or correct projections which did not terminate on their designated targets. (See the next item.)

c) Variance 80P-0157, Condition 9. The laser light show design failed to ensure that projections remained on their targets. Beams were observed missing the screens and projecting into navigable airspace for several of the

effects. Specifically the starfield effect and the diffraction grating effect and some of the scanned graphics were observed missing the screens during the shows on May 31 and June 1, 1998. In addition it is alleged that some projections illuminated an F-18 while flying westbound at 15000 feet descending to 10000 feet MSL toward Naval Air Station Miramar on Wednesday May 20, 1998, about 9:50 p.m.

d) Variance 80P-0157, Condition 11. The compliance assurance (QC) procedures were inadequate to assure that laser projections remained within their target areas and did not overfill or miss the designated targets. It was observed that only the fixed beam effects were even being checked for alignment with their targets and no checks were made on the other effects.

e) Variance 80P-0157, Condition 12.b. The Federal Aviation Administration was not notified of this laser light show either as an ongoing activity or even just for its setup activity. Even when a show is designed to be terminated, outdoor shows must provide FAA a notice of at least their setup activities, since one cannot presume that the projections will automatically be on target from the first.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. The production or performance of a laser light show is considered to be an act of manufacturing. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA.

You are not being requested to submit a formal corrective action plan at this time, however, all of your equipment and future performances must comply with the Federal performance standard/variance. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and evidence within 15 days of receipt of this letter.

You must respond to each of the items listed above stating what actions you will take and what changes you will make to your equipment or shows to achieve full compliance. Your response must cover:

a) design changes that will constrain all projections to terminate within their specific target areas (screens, mirrors, termination points);

b) documentation of the type of laser safety training provided for the operators;

c) changes to the daily compliance assurance check procedures (QC procedures) to verify that all projections are terminating on their targets and to assure that the operator will recognize any projections which are not terminating on their targets and make needed corrections; and

d) documentation of the notification to and response from the Federal Aviation Administration concerning this laser light show.

Your response should be submitted as a supplement to your report within 15 days of receipt of this letter, clearly referencing the appropriate accession number.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19900 MacArthur Blvd., Suite 300, Irvine, CA 92612. If you have further questions regarding these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spears for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health